

**DRAFT PROCESS CAPABILITY, CONTROL & IMPROVEMENT
REQUIREMENTS
(1/5/07)**

a. The Contractor shall establish a Process Control System that includes procedures, systems and software that provide control over production processes. This Process Control System shall complement the requirements of an ISO 9001-2000 or equivalent Quality Management System as well as all contract quality requirements. Statistical Process Control (SPC), when utilized, shall be implemented in accordance with ISO 11462-1 and ANSI/ASQC B1, B2, and B3. A Process Control Plan (PCP) shall be submitted to the Government for review and approval as stipulated per the DD Form 1423 and DI-MGMT-80004. Demonstration of process capability in accordance with approved PCP shall be accomplished prior to production and acceptance of product shall be based on verification of process capability in accordance with approved PCP.

b. Key characteristics are those characteristics identified in TDP documentation as critical and major plus any contractor selected characteristics. The contractor shall analyze all process and operation parameters affecting key characteristics for application of Process Control techniques unless otherwise required by check mark:

(1) ☐ Key characteristics and/or tools, techniques and control methods to be applied are those listed in paragraph g as tailorable characteristics. Alternate control methods can be suggested by the contractor but require Government approval.

(2) ☐ Key characteristics are _____ characteristics or identified process or operations parameters resulting from PFMEA of entire process. Government reserves the right to identify the specific characteristic, process, or operation parameters from the PFMEA as a key characteristic.

c. The contractor's analysis shall include processes and operations under the control of the prime contractor and those under the control of subcontractor or vendor facilities. The contractor shall create a process flow chart for the entire process and perform Process Failure Modes and Effects Analysis (PFMEA) for all processes identified on the process flow chart. The contractor shall identify, define, and delineate specific controls applicable for each process and operation that affects

key characteristics. The contractor shall conduct process capability studies and Repeatability & Reproducibility (R & R) studies for measurement systems on all process and operation parameters affecting key characteristics.

d. The contractor shall prepare and implement a Process Control Plan (PCP). This PCP shall be based upon and include results of process flow chart and PFMEA, and process capability studies and R & R studies for all process and operation parameters affecting key characteristics. The PCP shall address control methods, process and inspection equipment, action plan for out of control conditions, and process capability at stated production rate. Capable processes shall be one of the criteria for Government acceptance of product. When utilizing statistical methods, a Cpk index (a type of process capability index sensitive to whether the process is centered, but insensitive to special cause) shall be calculated. A Capable process for each process and operation parameter that affects key characteristics shall have a Cpk greater than or equal to 1.0 or as stated as follows: _____.

e. When the process or operation parameter under control has demonstrated both stability and capability, the Contractor may request in writing that inspection or testing performed in accordance with contract requirements be reduced or eliminated in accordance with MIL-STD-1916. At least three (3) consecutive lots or as stated as follows _____ *shall* have been inspected and accepted before reduction/elimination is requested.

f. All Corrective Action Requests (CARs) and Requests For Deviation (RFDs) generated for identification of product nonconformances shall result in the addition of characteristics to contractually required key characteristic list and require implementation of actions per paragraphs (c) and (d) above with submittal to the PCO for Government approval. If the CARs and RFDs are relating to characteristic, processes or operations already identified in the PCP then those actions required by paragraph (c) and (d) will be reassessed and submitted to the PCO for Government approval. The Government reserves the right to withhold acceptance of product until the revised PCP is approved by the Government.

g. If box b(1) was checked above, the tailored key characteristics and/or tools, techniques and control methods are specified as follows: